

**From:** Dang, Jiyoung M <jiyoung.dang@fda.hhs.gov>  
**Sent:** Fri, 10 Aug 2007 18:34:04 GMT  
**To:** Lisa, Bryan [ETHUS]  
**CC:** Krause, David <david.krause@fda.hhs.gov>; Dang, Jiyoung M <jiyoung.dang@fda.hhs.gov>  
**Subject:** RE: K071512 S01

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Dear Bryan,

We have reviewed your add-to-file (A01) document for K013718. We have determined that the shape changes made to the originally cleared Gynemesh are significant and did require the submission of a 510(k). However, we have decided that rather than have you submit a new 510(k), we will include this add-to-file as an amendment to K071512. The information you have provided in your add-to-file has now been logged in as K071512/A01 and will be reviewed as part of K071512.

Thank you,  
Jiyoung

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